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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,434	01/13/2006	Cinderella Christina Gerhardt	f7683 (V)	6803

201 7590 08/02/2007

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EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
08/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,434	GERHARDT ET AL.	
	Examiner	Art Unit	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/08/2007 has been entered. The preliminary amendment filed 7/27/2007 has also been entered. Claims 1-13 and 15 are pending.

Specification

2. The disclosure is objected to because of the following informalities: a separate section titled "A Brief Description of the Drawings" is missing. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. Applicant's arguments, see page 5, filed 3/08/2007, with respect to the rejection(s) of claim(s) 1-14 under 35 U.S.C. 102(b) for being anticipated by O'Callaghan *et al.* (WO 93/04593) and 35 U.S.C. 102(e) for being anticipated by Gerhardt *et al.* (U.S. Publication No. 2005/0238694) have been fully considered and are persuasive in light of the amendment to claim 1. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-13 and 15 are rejected under 35 U.S.C. 103(a) for being unpatentable over Reimer *et al.* (WO 01/37850) in view of O'Callaghan *et al.* (WO 93/04593). Reimer *et al.* teach a method of treatment of diabetes comprising administering an effective amount of a composition comprising sweet or acid whey proteins or hydrolysate (page 1, lines 11-14). The sweet or acid whey taught by Reimer *et al.* comprises whey protein hydrolysates and minor proteins that remain intact (page 8, lines 4-8) and is capable of stimulating the release of active GLP-1 in the NCI-H716 intestinal cell line (page 15, lines 11-23). The composition taught by Reimer *et al.* may be in the form of a powder, liquid concentrate or ready-to-drink beverage (page 10, lines 23-25) or in the form of fermented milk, yogurt, cheese, confectionary bar, breakfast cereal flakes or bars, drinks, milk powders, soy-based products or nutritional supplements for clinical nutritional supplements (page 10, lines 29-33).

6. Reimer *et al.* do not teach that the average molecular weight of the whey protein hydrolysate is in the range of 1000-12000 Daltons, that the whey protein hydrolysate comprises hydrolysates of β-lactoglobulins, α-lactalbumin or a mixture thereof, or that the degree of hydrolysis is in the range of 0.1% to 80% by weight.

7. O'Callaghan *et al.* teach hypoallergenic whey protein hydrolysate for use in infant formula (page 6, line 28) prepared by proteolytic treatment (page 6, line 33). The whey protein

hydrolysate has an average molecular weight of 1854.7 Daltons (the weighted average molecular weight based on the molecular weight distribution reported in Table 4). The whey protein hydrolysate taught by O'Callaghan *et al.* comprises lactalbumin hydrolysate (Table 4). Assuming a molecular weight of 16,000 Daltons for α-lactalbumin, the degree of hydrolysis of the whey protein in this composition is 11% (Table 4).

8. It would have been obvious to use the hypoallergenic whey protein hydrolysate taught by O'Callaghan *et al.* in place of the sweet or acid whey protein in the method of treating diabetes as taught by Reimer *et al.* In particular, it would have been obvious to orally administer this composition to subjects suffering from Type 2 diabetes or glucose intolerance and in doing so, improve or prevent a decline in mental performance, provide a sustained feeling of energy and maintain or provide a feeling of well-being during the post-prandial period in the same subjects. The skilled artisan would have been motivated to substitute the hypoallergenic whey protein hydrolysate taught by O'Callaghan *et al.* for the sweet or acid whey protein in the method of treating diabetes taught by Reimer *et al.* based on the teaching of Reimer *et al.* that the sweet or acid whey can be further hydrolyzed, for example to prepare a hypoallergenic whey protein hydrolysate (page 8, lines 16-18). The skilled artisan would have been motivated to target Type 2 diabetics and patients with impaired glucose tolerance (diabetics) based on the teachings of Reimer *et al.* Specifically, Reimer *et al.* discuss that Type II diabetics suffer from insulin resistance and that diabetics in general are aided by receiving controlled amounts of insulin (page 1, lines 31-36). Reimer *et al.* then comment that insulin injection is not as safe, convenient or acceptable to the patient as oral administration (page 2, lines 1-6). Reimer *et al.* go on to say that compositions that induce the release of glucagon-like-peptide-1 (GLP-1), a potent insulin

secretagogue (page 2, line 10), can be used to improve glucose homeostasis *in vivo*. Finally, Reimer *et al.* teach that sweet or acid whey, which can be administered orally, is capable of stimulating the release of active GLP-1 in the NCI-H716 intestinal cell line (page 15, lines 11-23). There would have been a reasonable expectation that the substitution of the whey protein hydrolysate taught by O'Callaghan *et al.* for that of Reimer *et al.* would be successful given that the whey protein hydrolysate taught by O'Callaghan *et al.* is also designed or oral administration to humans.

9. The combination of the Reimer *et al.* and O'Callaghan *et al.* references satisfy all of the limitations of claim 1: an edible composition comprising whey protein hydrolysate with an average molecular weight between 1000 and 12000 Daltons is orally administered to subjects suffering from Type 2 diabetes or glucose intolerance (all diabetics). Because the composition and patient population are identical to the claimed invention, the effects of improving or preventing a decline in mental performance, providing a sustained feeling of energy and maintaining or providing a feeling of well-being during the post-prandial period will result. With respect to claims 2 and 8, the whey protein hydrolysate comprises α-lactalbumin. With respect to claim 3, the whey protein hydrolysate has a degree of hydrolysis in the range of 1% to 20%. With respect to claims 5-9, 12 and 13, the compositions may be in the form of a powder, liquid concentrate or ready-to-drink beverage, fermented milk, yogurt, cheese, confectionary bar, breakfast cereal flakes or bars, drinks, milk powders, soy-based products or nutritional supplements for clinical nutritional supplements and are therefore designed a meal replacement products to be used as part of a diet plan to maintain glucose homeostasis (Reimer *et al.*, page 3, line 4).

10. Regarding claims 4 and 15, Reimer *et al.* teach that compositions comprise at least 0.01% sweet or acid whey by weight which differs from the claimed range of 0.1% to 80%, preferably 1% to 30%. It would have been obvious to the skilled artisan to optimize the concentration of whey protein hydrolysate in the composition in order to effectively induce GLP-1 secretion and control glucose homeostasis in the subject. Section 2144.05 of the MPEP states: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

11. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Marchetti Bradley, Ph.D.

Patent Examiner
Art Unit 1654

cmb

CECILIA TSANG
SUPERVISORY PATENT EXAMINER